K083706

FEB - 6 2009

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Information

Abbott Vascular (351931722)
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Contact Person

Nadine Smith, Regulatory Affairs Associate

Date Prepared

January 20, 2009

Device Information

Trade Name: Hi-Torque Versacore Guide Wire
Common Name: Wire, guide, catheter
Device Classification: Class II

Summary of Substantial Equivalence

The subject device, Abbott branded Hi-Torque Versacore Guide Wire is the same device as the predicate device, Mallinckrodt branded Wholey Hi-Torque Guide Wire (which is manufactured by Abbott Vascular for distribution through Conidian/Mallinckrodt Medical, Inc.)

- Same intended use,
- Same operating principle,
- Same guide wire design,
- Same manufacturing processes,
- Same materials (excluding packaging and labeling),
- Same shelf life,
- Same sterilization method.

Device Description

The Hi-Torque Versacore Guide Wire is a core-to-tip designed wire which consists of a stainless steel core, Polytetrafluoroethylene (PTFE) coated stainless steel coils on the distal 100 cm of the core, and a polyethylene coating on the remainder of the core.

The core is tapered from the tip over 35cm in three successive steps in diameter until it reaches its full diameter for the Modified J Guide Wire and in two successive steps for the Floppy and the Standard Guide Wires.

The coil covers the grinds and is brazed to the core at the tip and 7.5 cm (nominal) from the tip. The distal tip is radiopaque with a nominal diameter of 0.035" or 0.025". The distal tip is also shapeable or has a preshaped "J".

Polyethylene coating covers the proximal end and is attached to the coil with medical grade glue (Cyanoacrylate Ester) to ensure a smooth transition from coil to coating. Silicon is used to coat the entire length of the polyethylene tubing.

The Hi-Torque Versacore Guide Wire comes in lengths of 145 cm, 175 cm, 260 cm and 300 cm. The 0.035" diameter wires that are 145 cm and 175 cm in length are extendable using the Loc® Guide Wire Extension. Each Hi-Torque Versacore Guide Wire is packaged with a 0.025"-0.038" Torque Device.

The Hi-Torque Versacore Guide Wire is placed in a pouch with a peel away adhesive label placed on the film side of the pouch. They are packaged with 5 pouched guide wires per chipboard box and 9 chipboard boxes per corrugated box.

Summary of Changes to Previously Cleared Device

Abbott Branding and labeling changes include:

- IFU changed to: 40# Opaque Offset Insheet Style
- Label change to: Electronic IFU
- Addition of a chipboard box (5 pouched guide wires in a box)
- Addition of Scotch Tape 600 for sealing chipboard box

Intended Use:

The Hi-Torque Versacore Guide Wire is intended for use in angiographic procedures to introduce and position diagnostic and interventional devices within the peripheral vasculature during percutaneous procedures. The wire can be torqued to facilitate navigation through tortuous vessels.

The Hi-Torque Versacore Guide Wire is not intended for use in coronary or neurovasculature.

Summary of Technological Characteristics Compared to Predicate Device:

No changes were made that could impact product performance. Only branding, packaging and labeling are affected by this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Abbott Vascular
c/o Ms. Nadine Smith
Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, CA 95054

FEB - 6 2009

Re: K083706
Trade/Device Name: High-Torque Versacore Guide Wire
Common Name: Catheter guide wire
Regulation Number: 21 CFR 870.1330
Regulatory Class: II
Product Code: DQX
Dated: January 23, 2009
Received: January 26, 2009

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083706

Device Name: Hi-Torque Versacore Guide Wire

Indications for Use:

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Prescription Use XX	or	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083706